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November 23, 2005

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November 23, 2005 (Date) — Ron J. Laby

Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Re: *SN 08/113,561 "METHODS AND COMPOSITIONS FOR THE PRODUCTION OF STABLY TRANSFORMED, FERTILE MONOCOT PLANTS AND CELLS THEREOF" by Thomas R. Adams, et al.;*
Our Ref. DEKM:055US; Client Ref. 51719 US 02

Commissioner:

Transmitted herewith for filing are:

1. A Reply Brief; and
2. A return postcard to acknowledge receipt of these materials. Please date stamp and mail this postcard.

Should any fees under 37 C.F.R. §§ 1.16 to 1.21 be required for any reason relating to the enclosed materials, the Commissioner is authorized to deduct said fees from Fulbright & Jaworski L.L.P. Account No.: 50-1212/DEKM:055US.

Respectfully submitted,

Ron J. Laby
Reg. No. 53,173

RJL/vv
Enclosures

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
Thomas R. Adams *et al.*

Serial No.: 08/113,561

Filed: August 25, 1993

For: METHODS AND COMPOSITIONS FOR THE PRODUCTION OF STABLY TRANSFORMED, FERTILE MONOCOT PLANTS AND CELLS THEREOF

Group Art Unit: 1638

Examiner: Fox, David T.

Atty. Dkt. No.: DEKM:055US

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11/23/05 Ron J. Luby
Date Ron J. Luby

REPLY BRIEF

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REPLY BRIEF

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Appellants hereby submit this Reply Brief in response to the Examiner's Answer dated September 23, 2005. The date for filing this Reply Brief is November 23, 2005. No fees are believed due in connection with this paper; however, should any fees be due the Commissioner is authorized to withdraw the appropriate fees from Fulbright & Jaworski Deposit Account No. 50-1212/DEKM:055US.

Please date stamp and return the attached postcard as evidence of receipt.

I. REAL PARTY IN INTEREST

The real party in interest is Monsanto Company, the parent company of wholly owned subsidiary DeKalb Genetics Corp.

II. RELATED APPEALS AND INTERFERENCES

Appeals have been filed in Serial Nos. 09/081,416, 09/732,439 and 10/171,498. These case are related to the current case, but concern transgenic plants transformed with different transgenes conferring different phenotypes and thus are not believed to be relevant to this appeal, but are identified here in the event they should be of interest to the Board. Ser. No. 09/081,416 is a divisional application of this case; Ser. No. 09/732,439 is a divisional of a CIP of this case; and Ser. No. 10/171,498 is a continuation of a continuation application that was a CIP of this application.

III. STATUS OF THE CLAIMS

Claims 1-68 were filed. Claims 1, 5-66 and 68 were canceled. Claims 2-4 and 67 are therefore currently pending and are the subject of this appeal.

IV. STATUS OF AMENDMENTS

No amendments were made subsequent to the Final Office Action.

V. SUMMARY OF CLAIMED SUBJECT MATTER

The invention relates to genetically transformed monocotyledonous plants. Specification at page 3, lines 10-13. More particularly, it relates to fertile, transgenic maize plants transformed with a DNA sequence encoding a fatty acid desaturase gene, wherein the DNA sequence is

capable of being transmitted to subsequent plant progeny and is expressed. Specification at page 306. Expression of the fatty acid desaturase yields plants with altered seed oil properties. Specification at page 45, lines 18-19.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

(A) Are claims 2-4 and 67 properly rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement?

(B) Are claims 2-4 and 67 properly rejected under 35 U.S.C. §112, first paragraph, as not being enabled by the specification?

Appellants note that the Final Office Action rejected claims 2 and 3 as indefinite under 35 U.S.C. §112, second paragraph, for depending upon a canceled claim. Appellants intend to correct the error by amendment upon the allowance of the case or reopening of prosecution and thus are not appealing the rejection.

VII. REPLY

A. The Claims Meet the Written Description Requirement

1. The Recent Federal Circuit Holding in *Capon v. Eshhar* Requires Reversal of the Rejection

Following the filing of Appellants' Brief, the Federal Circuit decided a case presenting similar facts to the current case the holding of which requires reversal of the written description rejection. *Capon v. Eshhar*, 418 F.3d 1349 (Fed. Cir. 2005). In particular, the issue presented in *Capon* was whether claims directed to chimeric genes having various nucleic acid components must be supported by a specific disclosure of the nucleic acid sequences that make up the chimeric genes when the sequences were known in the art. *Id.* at 1355. The Board of Patent

Appeals and Interferences had held that such a disclosure was required and found the claims invalid for lack of an adequate written description. The Board summarized its holding as follows:

> Here, both [parties to the interference] claim novel genetic material described in terms of the functional characteristics of the protein it encodes. Their specifications do not satisfy the written description requirement because persons having ordinary skill in the art would not have been able to visualize and recognize the identity of the claimed genetic material without considering additional knowledge in the art, performing additional experimentation, and testing to confirm results.

Id.

Both parties appealed and the Federal Circuit reversed, explaining that the written description requirement doe not "require a re-description of what was already known." *Capon v. Eshhar*, 418 F.3d 1349, 1358 (Fed. Cir. 2005). The Court discussed the cases relied upon by the Board for its decision, explaining that in *Lilly* "the cDNA for human insulin had never been characterized"; in *Fiers* "much of the DNA sought to be claimed was of unknown structure" and in *Amgen* "a novel gene was not adequately characterized by its biological function alone because such a description would represent a mere 'wish to know the identity' of the novel material." *See Id., citing Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559 (Fed. Cir. 1997); *Fiers v. Revel*, 984 F.2d 1164 (Fed. Cir. 1993) and *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200 (Fed. Cir. 1991). Finally, the Court explained that *University of Rochester* merely found that the description of the COX-2 enzyme itself did not serve to describe unknown compounds capable of selectively inhibiting the enzyme. *Id.* at 1358, citing *University of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 69 U.S.P.Q.2d 1886 (Fed. Cir., 2004). Based on this, the Federal Circuit held that:

> The 'written description' requirement states that the patentee must describe the invention; it does not state that every invention must be described in the same way. As each field evolves, the balance also evolves between what is known and

> what is added by each inventive contribution. Both Eshhar and Capon explain that this invention does not concern the discovery of gene function or structure, as in *Lilly*. The chimeric genes here at issue are prepared from known DNA sequences of known function. The Board's requirement that these sequences must be analyzed and reported in the specification does not add descriptive substance. The Board erred in holding that the specifications do not meet the written description requirement because they do not reiterate the structure or formula or chemical name for the nucleotide sequences of the claimed chimeric genes.

Id. at 1358

The same issue is presented here and the Examiner attempts to take the position rejected by the Federal Circuit. The Examiner also relies upon many of the same cases discussed by the Federal Circuit. As noted by the Federal Circuit, *Lilly*, *Amgen* and *University of Rochester* turned on the description of a novel substance and are distinguishable from the situation in which a known composition is merely a component of the claimed invention. Like in *Capon*, the current claims do not involve the discovery of new genes but rather relate to plants transformed with known genes. These genes were well known in the art as established in Appellants' Brief. Therefore, the position of the Examiner is untenable and reversal of the rejection is thus respectfully requested.

2. The Examiner's Answer Misstates the Relevant Law

The Examiner's Answer amplifies on the incorrect interpretations of the relevant authorities in an attempt to support the rejection. A further review of the facts and holdings of these cases reveals that, if anything, they directly support the written description of the claims, as explained below.

a) The Written Description Guidelines

The Examiner first asserts in an attempt to support the rejection that the Written Description Guidelines support the position that "claims drawn to products containing inadequately described components are themselves inadequately described." Answer at p. 8, 1st

full ¶. However, what the Examiner ignores is that the Written Description Guidelines require that written description be reviewed "from the standpoint of one of skill in the art at the time the application was filed" and "should include a determination of the field of the invention and the level of skill and knowledge in the art. MPEP §2163(II)(A)(2). *Citing Wang Labs. v. Toshiba Corp.*, 993 F.2d 858, 865, 26 USPQ2d 1767, 1774 (Fed. Cir. 1993)). The evidence presented in Appellants' brief reveals that fatty acid desaturase genes were in fact well known and that Appellants are not attempting to claim the genes themselves. Specifically, Exhibits A-G of Appellants' Brief demonstrate at least nine fatty acid desaturases known in the art as of the effective filing date. This evidence is more than adequate to demonstrate possession of fatty acid desaturases in the context of the claimed invention.

b) Amgen v. Chugai

The Answer asserts that the holding of *Amgen v. Chugai* supports the rejection because "the claims were not limited to isolated genes. Instead, the claims included *compositions* comprising the proteins encoded by those genes." (Emphasis in original); Answer, bridging pp. 8-9. The Examiner therefore apparently asserts that the situation in *Amgen* was analogous to the current case because the compositions as found in claims 3 and 6 of US 4,677,195 that were the subject of the suit were invalid due to lack of conception of the particular nucleic acid sequence. This is simply incorrect because the subject claims were not directed to a novel composition made up from a ***known*** ingredient, but rather were directed to pharmaceutical compositions that had as their very point of novelty the "homogeneous erythropoietin of claim 1" in the case of claim 3 and "the homogeneous erythropoietin of claim 4" in the case of claim 6. Accordingly, *Amgen's* holding of inadequate conception was made for claims directed to "the ***novel***...sequence which codes for EPO." (emphasis added) *Amgen v. Chugai*, 927 F.2d 1200,

1216-18 (Fed. Cir. 1991). Thus, *Amgen* cannot be read to support the rejection, as underscored by the *Capon* decision as described above.

c) ***Eli Lilly***

The Answer also attempts to bootstrap the holding of *Lilly* to the current case in a manner similar to that done for *Amgen* by asserting that claims to "compositions" were at issue. Answer at p. 9, 2nd ¶. However, the *Lilly* claims were invalidated for lack of written description because the very thing that was the ***point of novelty*** was not described in the art or specification. *Regents of the Univ. of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1567 (Fed. Cir. 1997). The holding of *Lilly* in fact makes this very distinction and directly contradicts the Examiner by stating that "naming a type of material generally known to exist, ***in the absence of knowledge as to what that material consists of***, is not a description of that material." *Id.* at 1568 (emphasis added).

d) ***University of Rochester***

The Answer also mistakenly asserts that *University of Rochester* supports the written description rejection by contending that the description in that case of the relevant compound (COX-2 inhibitors) by function or assay alone is analogous to the current claims. Answer at p. 10, first full ¶. For example, it is asserted that the phenotypic traits of the claimed plants "are analogous to the 'desired result of its use' prohibited by the Court" in the *Rochester* case. *Id.* However, a reading of this case reveals that the situation at issue is the opposite of the current situation and that the Federal Circuit recognizes this difference. The Federal Circuit in particular noted that the patent at issue was invalid for lack of written description because an inhibitor of COX-2 was not disclosed in the application and there was ***no pre-existing awareness in the art*** of such a compound exhibiting this activity. *See University of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 927, 69 U.S.P.Q.2d 1886 (Fed. Cir., Feb. 13, 2004) In the current case there is

such a pre-existing awareness in the art. If anything, the *Rochester* case therefore directly supports the written description of the claims.

e) *Bayer*

The Answer asserts that *Bayer* is relevant because the Court "did not recognize that Housey had possession of the drug products claimed by Bayer" and as "possession is also a written description issue, *Bayer* is eminently applicable to the instant situation." Answer at p. 11, 1st ¶. Applicants respectfully submit that this misunderstands the issue under consideration in *Bayer*. The issue was patent infringement under 35 U.S.C. §271(g), not written description. *Bayer v. Housey*, 340 F.3d 1367, 1371, 68 U.S.P.Q.2d 1001 (Fed. Cir. 2003). Any "possession" that may have been referred to was in the context of infringement and importation of information gained from patented drug screening assays, not §112. *Id.* at 1371. The case therefore has no relevance to the current written description rejection.

B. The Claims Are Enabled

The Answer attempts to counter the showing of enablement made in Appellants' Brief by asserting that (1) Stephanopoulos *et al.* (1993) and Post-Beittenmiller *et al.* (1989) showed that plant transformation for modifying fatty acid metabolism has generally not been successful and few organisms have had their metabolic pathways altered, (2) given unpredictability allegedly inherent in modifying fatty acid biosynthesis "it is highly unlikely that plant transformation with fatty acid desaturase genes would cause a multitude of phenotypes unrelated to fatty acid content", (3) the holding of *Genentech* supports the rejection, (4) the Ursin Declaration is not persuasive because of use of a "non-exemplified" method of maize transformation and simultaneous expression of two desaturases "one of which was mutated," and (5) Appellants

allegedly confirmed the veracity of the Examiner's argument by noting "past failures of others" in the Response of October 18, 2004. These are addressed in order below.

1. Stephanopoulos *et al.* (1993) and Post-Beittenmiller *et al.* (1989)

The Examiner asserts that Post-Beittenmiller *et al.* (1989) teach that transformation with an acyl carrier protein (ACP) failed to produce changes in fatty acid synthesis or accumulation and that Stephanopoulos *et al.* shows that "modification of fatty acid accumulation generally has not been successful" and thus the claims are not enabled. Answer at p. 15, 1st full ¶. A review of Post-Beittenmiller, however, reveals first that the reference concerned tobacco plants, which as a dicotyledonous species are widely diverged from the monocotyledonous species maize and thus any findings in this species cannot be directly applied to maize. Furthermore, Post-Beittenmiller in fact "demonstrated that the levels of [transgenic spinach ACP] in tobacco chloroplasts could be raised twofold to threefold above the endogenous tobacco ACP" and this increased total ACP levels 3-4 fold. p. 895, 2nd col., 2nd full ¶. The authors also noted that "approximately 5 to 20% of the spinach ACP-I expressed in tobacco leaves was in the C8-C18 acyl form (similar to levels detected in spinach), providing a clear demonstration that spinach ACP-I participated in tobacco fatty acid metabolism." *Id.* While it was indicated that an unknown process could have caused the finding, the simplest explanation was the participation of the heterologous spinach ACP in fatty acid synthesis, and in any event the finding showed a detectable phenotypic change. The reference therefore in no way contradicts enablement when taken with the teaching in the specification.

With respect to Stephanopoulos, this was a general review that did not focus on any particular species or transgene. The sections relied upon by the Examiner say no more than that some "metabolic engineering" efforts have met with success, while the authors are also aware of other efforts that yielded "marginal results." Again, however, even when the statement is taken

as true for purposes of argument, subjectively "marginal" results are irrelevant to the objective standard of enablement, particularly when viewed with the other examples that "met with success." The relevant standard is undue experimentation and even marginal success would satisfy this burden. The conclusions of the Examiner regarding these references are thus unfounded.

2. Specific phenotypes "unrelated to fatty acid type or content" are irrelevant

The Examiner asserts that the claims are non-enabled because "it is highly unlikely that plant transformation with fatty acid desaturase genes would cause a multitude of phenotypes unrelated to fatty acid type or content, such as changes in flower color, plant height, etc. as encompassed by the claims." Answer at p. 15, 2nd full ¶. The meaning and relevance of this statement are not understood by Appellants. The claims do not require a "multitude of phenotypes unrelated to fatty acid type or content." The occurrence of any such traits is therefore completely irrelevant. The claims merely require expression of a fatty acid desaturase gene to render the transgenic maize plant identifiable over the corresponding untransformed maize plant. The evidence presented by Appellants demonstrating expression of the fatty acid desaturases and working examples demonstrating expression of numerous other transgenes more than adequately demonstrate enablement for this subject matter and thus the comments of the Examiner are both irrelevant and unfounded.

3. *Genentech* is inapposite

The Answer asserts that Appellants' demonstration of the inapplicability of the *Genentech* ruling to the current facts was unpersuasive and that the case is "eminently applicable to the instant fact pattern." Answer at p. 16, 2nd full ¶. For example, it was asserted that in *Genentech* claims directed to a method of cleaving undisclosed conjugate proteins were not

enabled by a specification that merely suggested the desirability of the cleavage, given the disclosure of a DNA molecule encoding a particular growth hormone, together with knowledge in the art of cleavable fusion expression techniques. It was thus concluded that *Genentech* found that prior art knowledge of trypsin as a potential cleavage agent was insufficient to enable the claimed invention and that this is applicable to the current situation because "Appellant has provided even less information than the Genentech patent which the Court ultimately found invalid." Answer at p. 17, 1st ¶.

In *Genentech* the relevant items asserted to be missing from the specification were reaction conditions for making cleavable fusion expressions and steps for making hGH. 42 USPQ 2d 1001, 1004 (Fed. Cir. 1997). The Court rejected notions that these elements were in the prior art because, as of the filing date, there was not a single example of a human protein produced via cleavable fusion protein expression. *Id.* at 1006. This was despite the presence of human proteins in the art and a "great many researchers" attempting to produce recombinant proteins. *Id.* In addition, the specification did not describe "any detail whatsoever" about how to obtain the claimed hGH cleavable fusion expression. *Id.* at 1004. In contrast, the element that is alleged to be lacking here, fatty acid desaturase genes, was in fact well known as of the effective filing date as fully demonstrated in Appellants' Brief.

Exhibits A-G alone demonstrate at least nine examples of known fatty acid desaturases. In addition, the working examples provide detailed teaching demonstrating the successful transgenic expression of numerous foreign genes in maize. Table 8 of the specification, for example, states that fertile transgenic plants were obtained from 267 different transgenic lines. Table 9 shows that R0 transgenic plants were obtained expressing at least the following genes: a *uidA* reporter gene, a *bar* selectable marker gene conferring herbicide tolerance, a *hyg* gene

conferring resistance to hygromycin, an *aroA* gene conferring tolerance to the herbicide glyphosate, a *Bacillus thuringiensis* endotoxin gene, and a Z10 altered seed storage protein. Maize callus cells were also obtained transformed with a C1 anthocyanin pigmentation gene, a *lux* luciferase reporter gene, potato and tomato *pinII* proteinase inhibitor genes conferring insect resistance, an *mtlD* protein conferring enhanced stress resistance and a *deh* gene conferring resistance to dalapon herbicide. Given these examples, it would have been routine for one of skill in the art to express a fatty acid desaturase using the same methods and simply replacing any of the many coding sequences with the fatty acid desaturase sequence. These examples therefore fully demonstrate the enablement of the claims and lack of applicability of the *Genentech* holding.

4. The Ursin declaration demonstrates enablement of the claims

The Answer asserts that the Ursin Declaration is not persuasive because it used a "non-exemplified" method of maize transformation and simultaneous expression of two desaturases "one of which was mutated." Appellants initially note in response that the first assertion is completely irrelevant. The Examiner ***does not contest*** that Appellants' specification is enabling for maize transformation and the mode of introduction of the transgene is irrelevant to the issue of whether the transgene would express or cause phenotypic change. The end result is the introduction of the transgene into the genome of a maize plant regardless of the method used. The Examiner's allegations that the mode of transformation has any relevance to the ability to express the transgene and applicability of Ursin Declaration are therefore unsupported and incorrect.

Regarding the use of two transgenes or that one of them was "mutated," this also in no way negates the showing made by Dr. Ursin. If anything, it demonstrates the ability to express two transgenes, at least one of which was not "mutated." As stated by Dr. Ursin, the results

demonstrated that expression of a fatty acid desaturase gene in maize alters the fatty acid profile in a manner that renders the transgenic plants identifiable over a corresponding non-transgenic plants. Dr. Ursin also explains that the results confirm that the alteration of fatty acid profiles occurs in a ***predictable manner*** consistent with the enzymatic activity of the fatty acid desaturase that is introduced. Coupled with the numerous working examples in the specification demonstrating the ability to routinely and predictably express a diverse collection of transgenes in maize, this more than adequately demonstrates enablement.

5. Appellants Confirmation of "Past Failures of Others" does not negate enablement

The Answer concludes by asserting that "Appellants confirmed the veracity of the Examiner's arguments regarding lack of enablement" by referring to the past failures of others in the traversal of an obviousness rejection on page 9 of the Response to Office Action of October 18, 2004. The relevant section referred to the lack of engineering of grain composition traits in maize prior to applicants invention and the difficulty of others in engineering maize specifically, *e.g.*, the failure of the prior art to transform and express transgenes in maize. This section also quoted contradictory statements made by the Examiner. However, the past failures of others referred to was with respect to the ability to transform and express transgenes in maize, which problem the specification fully solves. In particular, the specification demonstrates the expression in maize cells of at least ***11 different transgenes and recovery of at least 267 different transgenic lines***. Specification Tables 8 and 9. In the case of 6 transgenes, transgenic plants were regenerated. The transgenes that were expressed were diverse in mode of action and phenotype conferred, and included genes conferring tolerance to multiple herbicides and antibiotics (*bar*, *hyg*, *aroA*, *deh*), insect resistance genes (*Bt*, tomato and potato *PinII*), a seed storage protein gene (*Z10*), screenable color or enzymatic reporter genes (*C1*, *uidA*, *lux*), and a

drought tolerance gene (*mtlD*). These examples more than adequately demonstrate that the specification enables the reliable and predictable expression of heterologous genes in maize without undue experimentation. Reversal of the rejection is thus respectfully requested.

In conclusion, the claims are fully enabled and the Examiner has presented no reasonable basis for concluding otherwise. Reversal of the rejection is thus respectfully requested.

VIII. CONCLUSION

It is respectfully submitted, in light of the above, that none of the claims are properly rejected. Therefore, Appellants request that the Board reverse the pending grounds for rejection.

Respectfully submitted,

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APPENDIX 1: LISTING OF APPEALED CLAIMS

1. (Canceled)

2. (Previously amended) Cells obtained from the plant of claim 67 or 68, wherein said cells comprise the DNA composition.

3. (Previously amended) Progeny of the plant of claim 67 or 68, wherein said progeny comprise the DNA composition.

4. (Previously amended) Seeds obtained from the plant of claim 3, wherein said seeds comprise the DNA composition.

5-66. (Canceled)

67. (Previously amended) A fertile, transgenic maize plant, the genome of which has been augmented by the introduction of a DNA composition comprising a gene encoding a grain composition trait comprising a fatty acid desaturase gene so that the transgenic plant exhibits one or more phenotypic characteristics that render it identifiable over the corresponding untransformed maize plant which does not comprise said gene, and wherein said gene is transmittable through normal sexual reproduction of the transgenic maize plant to subsequent generation plants.

68. (Canceled)